PUBLISH

UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

MINERAL RESOURCES INTERNATIONAL, a Business Trust; TRACE MINERAL RESEARCH, a Business Trust, Petitioners, v. UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES; DONNA E. SHALALA, Secretary, United States Department of Health and Human Services; UNITED STATES FOOD AND DRUG ADMINISTRATION; DAVID A. KESSLER, Commissioner of Food and Drugs, Food and Drug Administration; UNITED STATES OF AMERICA, Respondents.	No. 94-9523 94-9524 94-9525
CENTER FOR SCIENCE IN THE PUBLIC INTEREST, PUBLIC CITIZEN LITIGATION GROUP, AMERICAN HEART ASSOCIATION, AMERICAN CANCER SOCIETY AND THE CONSUMER FEDERATION OF AMERICA, Amici Curiae.	

Upon Petitions for Review
from the Department of Health & Human Services
(85N-061D, 91N-384D, 90N-135D)

Jonathan W. Emord of Emord & Associates, P.C., Washington, D.C., for Petitioner.

Susan Strawn (Gerald C. Kell with her on the brief), Office of Consumer Litigation, Civil Division, (Frank W. Hunger, Assistant Attorney General, Douglas Letter, Appellate Staff, on the brief), Washington, D.C., (Margaret Jane Porter, Chief Counsel, Philip S. Derfler, Associate Chief Counsel, Food and Drug Administration, Rockville, Maryland, of Counsel), for Respondent.

Bruce Silverglade, John M. Gleason of Center for Science in the Public Interest, Brian Wolfman, Allison M. Zieve of Public Citizen Litigation group, Washington, D.C., filed an amici curiae brief for the Center for Science in the Public Interest, Public Citizen, Inc., American Heart Association, American Cancer Society and the Consumer Federation of America.

Before: BALDOCK, EBEL and ALARCÓN,* Circuit Judges.

ALARCÓN, Circuit Judge.

Mineral Resources International and Trace Mineral Research (hereinafter "Minerals") seek review of regulations promulgated by the Federal Drug Administration ("FDA") under sections 343(q) and 343(r) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (Supp. V 1993). Minerals maintain that we have jurisdiction pursuant to 21 U.S.C. § 371(f) (1988 & Supp. V 1993). Minerals contend that the regulations violate their First and Fifth Amendment rights and the Administrative Procedures Act ("APA"), 5 U.S.C. § 706 (1988). We do not reach the merits of Minerals' assertions because we lack original jurisdiction to review the validity of regulations promulgated pursuant to sections 343(q) and 343(r).

I. BACKGROUND

In petition numbers 94-9523, 94-9524, and 94-9525, Minerals challenge the validity of the health claim regulation, the nutrient content regulation, and the nutrition labeling regulation, respectively. 59 Fed. Reg. 395 (1994) (codified at 21 C.F.R. § 20, 101); 59 Fed. Reg. 378 (1994) (to be codified at 21 C.F.R. § 101.54-101.69); 59 Fed. Reg. 363 (1994) (to be codified at 21 C.F.R. § 101.36). These regulations were promulgated by the FDA pursuant to the Nutrition Labeling and Education Act of 1990 ("NLEA"), Pub. L. No. 101-535, 104 Stat. 2353 (codified at 21

* Honorable Arthur L. Alarcón, United States Senior Circuit Judge for the Ninth Circuit, sitting by designation.

U.S.C. § 343(q), (r) (Supp. V 1993)) which amended the Federal Food, Drug, and Cosmetic Act. The NLEA added sections 343(q) and 343(r) to that Act.

II. JURISDICTIONAL CHALLENGE

On April 29, 1994, the FDA filed a motion to dismiss the petitions for lack of subject matter jurisdiction. The FDA asserts that the regulations Minerals challenge were promulgated under sections 343(q) and 343(r). The FDA argues that this court lacks jurisdiction to review a regulation promulgated pursuant to section 343(q) or 343(r), because these sections are not specifically set forth in 21 U.S.C. § 371(e) (1988 & Supp V. 1993).

In their opposition to the FDA's motion to dismiss, Minerals do not dispute the FDA's position that the regulations were promulgated under sections 343(q) and 343(r). Instead, Minerals advance discrete theories to support their contention that this court has original subject matter jurisdiction over their petitions. Minerals assert that section 371(f) expressly authorizes review of their petitions by this court. Further, Minerals contend that this court has original jurisdiction as a result of the 1990 amendment to 21 U.S.C. § 371(a) (1988). Additionally, Minerals insist that their petitions are properly before us because "the regulations in issue were promulgated not just pursuant to the NLEA but also pursuant to 21 U.S.C. § 371(a), the very statutory section that affords direct review in the United States courts of appeal." (emphasis in original). Minerals also argue that this court has original jurisdiction over their

petitions because the subject regulations affect foods for special dietary uses. Finally, Minerals maintain that public policy considerations justify the assertion by this court of original jurisdiction to review the regulations at issue in this matter.

III. ANALYSIS

Federal courts have limited jurisdiction. Henry v. Office of Thrift Supervision, 43 F.3d 507, 511 (10th Cir. 1994). We must dismiss any matter when "it becomes apparent that jurisdiction is lacking." Penteco Corp. v. Union Gas Sys., Inc., 929 F.2d 1519, 1521 (10th Cir. 1991) (citations omitted); Tuck v. United Servs. Auto. Ass'n, 859 F.2d 842, 844 (10th Cir. 1988), cert. denied, 489 U.S. 1080 (1989). "Since federal courts are courts of limited jurisdiction, we presume no jurisdiction exists absent a showing of proof by the party asserting federal jurisdiction." United States ex. rel. Precision Co. v. Koch Indus., Inc., 971 F.2d 548, 551 (10th Cir. 1992), cert. denied, 113 S. Ct. 1364 (1993) (citations omitted). Minerals have the burden of demonstrating that their petitions are properly before this court. We address each of Minerals' arguments under separate headings.

A. Original jurisdiction in this court pursuant to 21 U.S.C. § 371(f)

Minerals assert that we have original jurisdiction over their petitions pursuant to 21 U.S.C. § 371 (f)(1). We disagree.

21 U.S.C. § 371(f)(1)[1] provides that the United States Court

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[1] 21 U.S.C. § 371(f)(1) provides, in pertinent part that:

> In a case of actual controversy as to the validity of any order under subsection (e) of this section, any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth

of Appeals for "the circuit wherein any person affected resides or has his principal place of business" has original jurisdiction over challenges to regulations promulgated pursuant to the statutes expressly set forth in section 371(e)(1).[2] Section

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day after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order.

Id.

[2] 21 U.S.C. § 371(e) provides that:

> (1) Any action for the issuance, amendment, or repeal of any regulation under section 343(j), 344(a), 346, 351(b), or 352(d) or (h) of this title . . . shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable ground therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2) of this subsection, the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.
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> (2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subjection is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3) of this subsection, the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

371(e)(1) does not expressly refer to regulations that are promulgated under sections 343(q) and 343(r). The scope of section 371(e) is explicitly limited to "any regulation under section 343(j), 344(a), 346, 351(b), or 352(a) or (h) . . . ." 21 U.S.C. § 371(e)(1).

The FDA, pursuant to its general rule making authority established in section 371(a),[3] promulgated the health claim regulation, the nutrient content regulation, and the nutrition labeling regulation. In 1990, when Congress enacted the NLEA and directed the FDA to issue the instant regulations, it did not instruct the FDA to promulgate section 343(q) or 343(r)[4] pursuant

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> (3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

Id.

[3] 21 U.S.C. § 371(a) provides that: "[t]he authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary."

[4] Public Law No. 101-535, as amended by Public Law No. 102-571 provides, in pertinent part that:

> Regulations.--

to 21 U.S.C. § 371(e). We agree with the Second Circuit that when Congress wants regulations to be promulgated pursuant to the procedures set forth in 21 U.S.C. § 371(e), it has demonstrated

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> (1) The Secretary of Health and Human Services shall issue proposed regulations to implement section 403(q) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(q)] within 12 months after the date of the enactment of this Act [Nov. 8, 1990], except that the Secretary shall issue, not later than June 15, 1993, proposed regulations that are applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances to implement such section. Not later than 24 months after the date of the enactment of this Act, the Secretary shall issue final regulations to implement the requirements of such section, except that the Secretary shall issue, not later than December 31, 1993, such a final regulation applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances.
> . . . .
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> (1)(A) Within 12 months of the date of the enactment of this Act [Nov. 8, 1990], the Secretary of Health and Human Services shall issue proposed regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(r)], except that the Secretary shall issue, not later than June 15, 1993, proposed regulations that are applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances to implement such section.
> . . . .
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> (B) Not later than 24 months after the date of the enactment of this Act, the Secretary shall issue final regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act, except that the Secretary shall issue, not later than December 31, 1993, such a final regulation applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances. . . .

21 U.S.C. § 343 note (Supp. V 1993) (Regulations for implementation of paragraphs (q) and (r)).

that it knows how to do so. National Ass'n of Pharmaceutical Mfrs. v. FDA, 637 F.2d 877, 887 (2d Cir. 1981). Minerals have not met their burden of demonstrating that section 371(f) confers original jurisdiction in this court to review regulations promulgated under sections 343(q) and 343(r).

B. Effect of the 1990 amendment of section 371(e) on this court's jurisdiction over regulations promulgated under sections 343(q) and 343(r)

Minerals contend that Congress has conferred jurisdiction in this court over the challenged regulations notwithstanding the fact that sections 343(q) and 343(r) are not specifically set forth in section 371(e). Minerals assert that in 1990, when Congress enacted the NLEA, it chose not to amend section 371(e). Accordingly, Minerals assert that Congress "found nothing in Section 371 that needed to be changed and so [it] left that section untouched." It would appear that Minerals believe that we can imply from the failure to modify section 371(e) that Congress intended to confer original jurisdiction on this court to review regulations promulgated pursuant to sections 343(q) and 343(r).

The only support Minerals cite for this proposition is Judge Malcolm Richard Wilkey's dissent in Independent Cosmetic Mfrs. and Distrib. Inc. v. United States Dep't of Health, Educ. and Welfare, 574 F.2d 553 (D.C. Cir.), cert. denied, 439 U.S. 893 (1978). Minerals' reliance on Judge Wilkey's dissent does not advance their cause. In his dissenting expression, Judge Wilkey pointed out that: "[t]here is no special statutory review procedure (i.e.,

court of appeals review) applicable to regulations promulgated pursuant to § 701(a)."[5] Id. at 574 (Wilkey, J., dissenting).

Minerals' theory is contrary to existing Supreme Court and Tenth Circuit authority. As noted above, federal courts can only exercise that jurisdiction conferred upon them by Congress. Henry, 43 F.3d at 511; Penteco Corp., 929 F.2d at 1521; Tuck, 859 F.2d 844. We are "reluctant to infer new legislative provisions out of [Congressional] silence." Quivira Mining Co. v. United States E.P.A., 728 F.2d 477, 483 (10th Cir. 1984).

C. No original jurisdiction in this court over regulations promulgated under the FDA's general rule making authority

Minerals claim that this court has original jurisdiction over their petitions because the FDA enacted the regulations that are the subject of their petitions pursuant to 21 U.S.C. § 371(a), which grants the FDA its general rule making authority. Minerals have failed to cite any case to support this theory.

The Second Circuit, in discussing which court has jurisdiction to review a regulation promulgated pursuant to section 371(a), reasoned that "the FDA's general authority 'to promulgate regulations for the efficient enforcement' of the statute, must be challenged in the district court." National Nutritional Foods Ass'n v. FDA, 504 F.2d 761, 772 (2d Cir. 1974), cert. denied, 420 U.S. 946 (1975). We agree. We do not have original jurisdiction over Minerals' petitions based upon section 371(a).

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[5] Section 701(a) of the Federal Food, Drug, and Cosmetic Act is codified at 21 U.S.C. § 371(a).

D. Foods for special dietary uses

Minerals argue that we have original jurisdiction over their petitions because regulations promulgated under sections 343(q) and 343(r) affect "foods for special dietary uses," which are governed by 21 U.S.C. § 343(j) (1988).[6] Regulations promulgated under section 343(j) are subject to original review by this court pursuant to section 371(f).

The only support that Minerals cite for this proposition is a terse passage in their opposition to the FDA's motion to dismiss which states as follows:

> The foods in issue, particular nutrient supplements designed for and used by those in the at-risk categories (who either have or are susceptible to having certain debilitating illnesses and conditions, including neural tube defects, cardiovascular disease and cancer) are special dietary use foods within the meaning of 21 U.S.C. §343(j). See generally 21 U.S.C. § 350(c)(3)(A) [(1988)] and United States v. Undetermined Quantities of an Article of Drug Labeled as "Exachol", 716 F.Supp. 787, 792 (D.C. [sic] S.D.N.Y. 1989). Consequently, the statute does apply to vest jurisdiction over this appeal in this Court.

(emphasis in the original).

Minerals do not offer any argument in support of their theory that section 350(c)(3)(A) or Exachol can be interpreted to confer original jurisdiction over their petitions. Section 350(c)(3)(A)[7]

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[6] 21 U.S.C. § 343 provides that a food is misbranded:

> (j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order to inform purchasers as to its value for such uses.

Id.

[7] 21 U.S.C. § 350(c)(3) states that "special dietary use"

merely defines "foods for special dietary uses." It does not contain any support for Minerals' contention that regulations promulgated under sections 343(q) and 343(r) are subject to original review by this court. Exachol was decided in 1989, prior to the enactment of the NLEA in 1990. Exachol does not address the question whether this court has original jurisdiction over petitions challenging regulations promulgated under sections 343(q) and 343(r).

When the FDA promulgated the health claim regulation, the nutrient content regulation, and the nutrition labeling regulation, it was following the Congressional mandate to issue these regulations as authorized under sections 343(q) and 343(r). Assuming that sections 343(q) and 343(r) may incidentally affect foods for special dietary uses, only Congress has the power to confer jurisdiction on this court to review, in the first instance, challenges to regulations promulgated under these statutes.

E. Public policy does not support original jurisdiction over Minerals' petitions

Finally, Minerals maintain that public policy warrants direct appellate review of their petitions. Minerals argue

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includes, but is not limited to the following:

> (A) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium.

Id.

that we must adjudicate their petitions to prevent duplicative litigation in district courts across the nation. Minerals assert that judicial economy weighs against having a trial court adjudicate their petitions because their petitions raise legal issues which will have to be decided de novo in this court. Minerals' public policy argument ignores the principle that this court lacks jurisdiction over a subject matter unless it is conferred by Congress. Henry, 43 F.3d at 511. Public policy considerations of judicial economy cannot be relied upon to expand our jurisdiction in the absence of express Congressional authority.

The petitions are DISMISSED.